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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/005,202      | 12/04/2001  | Keith D. Allen       | R-902               | 6809             |



7590 05/22/2003  
DELTAGEN, INC.  
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EXAMINER

WILSON, MICHAEL C

ART UNIT PAPER NUMBER

1632

DATE MAILED: 05/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.





# Office Action Summary

Application No.

10/005,202

Applicant(s)

ALLEN, KEITH D.

Examiner

Michael C. Wilson

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☒ Other: *Notice to Comply*.

Claims 1-28 are pending and under consideration.

The computer readable format of the sequence listing filed had errors, but was entered by STIC. The disk had non-ASCII "garbage" at the beginning/end of files that were deleted by STIC.

### ***Specification***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The sequence in Fig. 3 is not described in the sequence listing originally filed. A new CRF and paper listing is required with the new sequence. The number should be incorporated into the description of the sequence on pg 8, line 18.** Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing." Applicant is requested to return a copy of the attached Notice to Comply with the reply. Failure to fully comply with the sequence rules in response to the instant office action will be considered non-responsive.

The specification should clearly describe Fig. 3 on pg 8, line 18. The description of Fig. 4 should be separate.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 2, drawn to a targeting construct comprising a first and second polynucleotide sequence encoding a portion of a Kir5.1 gene and a selectable marker, and a method of making a targeting construct by providing a first and second polynucleotide sequence encoding a portion of a Kir5.1 gene, and a selectable, classified in class 435, subclass 320.1.
- II. Claims 3-12 and 14-25, drawn to a cell having a disruption in a Kir5.1 gene, a non-human transgenic animal having a disruption in a Kir5.1 gene, a method of making the animal and a method of using the animal, classified in class 800, subclass 8, et al.
- III. Claims 13 and 26, drawn to agents that treat disease, classified in various classes and subclasses.
- IV. Claim 27, drawn to an antagonist of Kir5.1, classified in various classes and subclasses.
- V. Claim 27, drawn to agonists of Kir5.1, classified in various classes and subclasses.
- VI. Claim 28, drawn to phenotypic data, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not used together. The targeting construct does not have a disruption in the Kir5.1 gene while the cells and animals of Invention II require a disruption in the Kir5.1 gene.

Inventions I and III are unrelated. The protocols and reagents required for targeting constructs are materially distinct and separate from those required for agents used to treat diseases associated with a disruption in a Kir5.1 gene. The agents do not require the targeting construct and vice versa.

Inventions I and IV or V are unrelated. The protocols and reagents required for targeting constructs are materially distinct and separate from those required for agonists or antagonists of Kir5.1. The agonists or antagonists of Kir5.1 do not require the targeting construct and vice versa.

Inventions I and VI are unrelated. The protocols and reagents required for targeting constructs are materially distinct and separate from those required for data. The data does not require the targeting construct and vice versa.

Inventions II and III are unrelated. The protocols and reagents required for cells and transgenic animals having a disruption in a Kir5.1 gene are materially distinct and separate from those required for agents used to treat diseases associated with a disruption in a Kir5.1 gene. The agents do not require the cells or animals and vice versa.

Inventions II and IV or V are unrelated. The protocols and reagents required for cells and transgenic animals having a disruption in a Kir5.1 gene are materially distinct and separate from those required for agonists or antagonists of Kir5.1. The agonists or antagonists of Kir5.1 do not require the cells or animals and vice versa.

Inventions II and VI are unrelated. The protocols and reagents required for cells and transgenic animals having a disruption in a Kir5.1 gene are materially distinct and separate from those required for data. The data does not require the cells or animals and vice versa.

Inventions III and IV or V are unrelated. The protocols and reagents required for agents that treat a disease associated with a disruption in a Kir5.1 gene are materially distinct and separate from those required for agonists or antagonists of Kir5.1. The agonists or antagonists of Kir5.1 do not require the agents and vice versa.

Inventions II and VI are unrelated. The protocols and reagents required for agents that treat a disease associated with a disruption in a Kir5.1 gene are materially distinct and separate from those required for data. The data does not require the agents and vice versa.

Inventions IV and V are unrelated. Antagonists inhibit the function of Kir5.1 while agonists increase the function of Kir5.1. Antagonists and agonists have different modes of operation as they have different structures and bind to Kir5.1 differently. Antagonists of Kir5.1 do not require agonists of Kir5.1 and vice versa.

Art Unit: 1632

Inventions IV or V and VI are unrelated. The protocols and reagents required for antagonists or agonists of Kir5.1 are materially distinct and separate from those required for data. The data does not require the antagonists or agonists and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I-VI is separate, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



**MICHAEL WILSON**  
**PRIMARY EXAMINER**